

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

BIOGEN INTERNATIONAL GMBH and
BIOGEN MA INC.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS LLC, *et al.*,

Defendants.

1:17-cv-00823-LPS (consolidated)

(1:17-cv-00853)

STIPULATION AND ORDER STAYING

Biogen International GmbH, et al. v. Lupin Atlantis Holdings SA, et al.

Plaintiffs Biogen International GmbH and Biogen MA Inc. (collectively, “Biogen” or “Plaintiffs”) brought the following action against defendant Lupin Atlantis Holdings SA and Lupin Inc. (collectively, “Lupin” or “Defendants”), alleging infringement of U.S. Patent Nos. 6,509,376 (“the ’376 patent”), 7,320,999 (“the ’999 patent”) and 8,399,514 (“the ’514 patent”) (collectively, the “Asserted Patents”): *Biogen International GmbH, et al. v. Lupin Atlantis Holdings SA et al.*, Case No. 1:17-cv-00853, filed June 28, 2017 (“the 17-853 Action”). The Court later consolidated this action with *Biogen International GmbH, et al. v. Amneal Pharmaceuticals LLC*, Case No. 1:17-cv-00823-LPS (the “Dimethyl Fumarate Consolidated Action”).

Biogen and Lupin stipulate to a stay of the 17-853 Action in accordance with the terms and conditions set forth herein.

IT IS HEREBY STIPULATED, subject to the approval of the Court:

1. Lupin stipulates to infringement of the ’376, ’999 and ’514 patents.
2. Biogen and Lupin agree to be bound by the Judgment of the District Court for the District of Delaware (“District Court”) in the Dimethyl Fumarate Consolidated Action as to the

validity and/or enforceability of the Asserted Patents in connection with the Lupin ANDA Product, and agree that such Judgment will be res judicata as to Biogen, Lupin, and the 17-853 Action to the extent it is not reversed, vacated or modified on appeal.

3. The 17-853 Action is stayed in its entirety pending final disposition, i.e., final judgment concerning the Asserted Patents from which no appeal may be taken, other than a petition to the Supreme Court for a writ of certiorari in the Dimethyl Fumarate Consolidated Action (excluding judgment that is entered as a result of settlement, consent judgment, stipulated judgment, sanctions, procedural default, or other judgment or disposition that is not an actual contested decision on the merits of the Action).

4. A statutory stay of FDA approval of Lupin's ANDA No. 210226 is currently in effect pursuant to the Hatch-Waxman Act, and the stay of the 17-853 Action shall have no effect on this statutory stay of FDA approval imposed under the Hatch Waxman Act.

5. Notwithstanding the foregoing, Biogen may lift the stay of the 17-853 Action for the purpose of seeking injunctive relief in the event of an actual or threatened launch by Lupin of a dimethyl fumarate product upon expiration of the statutory stay of FDA approval while the Dimethyl Fumarate Consolidated Action is still pending.

6. If the Court were to lift the stay of the 17-853 Action for any other reason, the 17-853 Action will proceed on the same schedule as the Dimethyl Fumarate Consolidated Action and on the same record as developed at the time the Court lifts the stay of the 17-853 Action.

7. Any Judgment in the Dimethyl Fumarate Consolidated Action shall be entered in the 17-853 Action at the same time as entered in the Dimethyl Fumarate Consolidated Action.

8. Any Judgment entered in the Dimethyl Fumarate Consolidated Action concerning exceptional case under 35 U.S.C. § 285 or costs under 28 U.S.C. § 1920 shall not be entered in the

17-853 Action. Both parties have agreed to waive any claim for attorneys' fees and/or costs against the other in the 17-853 Action.

9. The obligations imposed on Biogen and Lupin by this Stipulation shall be binding upon Biogen and Lupin and their respective parents, subsidiaries, affiliates and successors, including any successor in interest to Lupin's ANDA No. 210226.

10. This Stipulation grants no rights to Lupin under any patents or other proprietary rights.

Dated: July 31, 2018

Respectfully submitted,

/s/ Steven J. Balick

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
ASHBY & GEDDES
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-188
sbalick@ashby-geddes.com
amayo@ashby-geddes.com

*Attorneys for Plaintiffs/Counterclaim
Defendants Biogen International GmbH
and Biogen MA Inc.*

Of Counsel:

James B. Monroe
Li Feng
Sanya Sukduang
Andrew E. Renison
Jeanette M. Roorda
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Ave., N.W.
Washington, D.C. 20001
(202) 408-4000

/s/ Kelly E. Farnan

Kelly E. Farnan
Richards, Layton & Finger, PA
One Rodney Square
Suite 600
920 N. King Street
Wilmington, DE 19801
(302) 651-7705
farnan@rlf.com

*Attorney for the Defendants/Counterclaim
Plaintiffs*

Of counsel:

Imron T. Aly
Schiff Hardin LLP
233 S. Wacker Dr., Suite 7100
Chicago, IL 60606
(312) 258-5500
ialy@schiffhardin.com

Christopher M. Bruno
Schiff Hardin LLP
901 K Street NW, Suite 700
Washington, DC 20001
(202) 778-6400
cbruno@schiffhardin.com

Based on the foregoing stipulation, IT IS SO ORDERED.

Dated: _____

Hon. Leonard P. Stark, Judge
United States District Court
District of Delaware